PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ekapot Bhunachet, M.D.,PhD

Applicant No. 09/936,872

Title: "FLUORESCENCE ELETRONIC ENDOSCOPIC SYSTEM"

U.S. Filing Date: September 17, 2001

Reply to the action filed on February 9, 2005

Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

Sir:

I, the applicant, consider that the claim rejections are not correct based on the following reasons:

1. The invention of Wagnieres et al. has different principle from my invention. In their invention, the auto-fluorescence light reflected by the tissue is split into a green and spacially separated from this, a red spectral component and falls each on one half of a black and white CCD to be processed into two separate processing channels, which are finally displayed on the monitor by green and red channels, respectively. In my invention, the green and red auto-fluorescence light, after passing the barrier filter to cut off the blue excitation light, fall on the same place of a black and white CCD and are processed as a total to one channel, for example blue channel, and finally superimposed with the background image processed by the other two channels, i.e. green and red channels, provided by non-excitation green and red light.

   With their principle in which two diacritic mirrors and two filters (see

col. 2, lines 46-61) are needed as the color splitter, it is impossible to place this color splitter and a black and white CCD into the tip (distal end) of an endoscope. Their system can function only by being combined with a fiber-scope (see col. 4, lines 7-9). Compared to the invention of MacAulay et al. in which commonly two color cameras are used, the invention of Wagnieres et al. is able to diminish the size of the head piece attached onto the eyepiece part of a fiber-scope, thus may lower the price and improve the handling of the endoscope (see col. 1, lines 59 – 67). As mentioned in my previous argument, my invention is developed based on an electronic (or video) endoscopic system with a black and white CCD sensor placed at the tip of the scope (Olympus), practically just by placing a barrier filter in front of the objective lens and a glass adjuster filter in the existing filter holder within the light source. This OLYMPUS electronic endoscpic system has widely been used throughout Japan and other countries for almost twenty years. Thus, my invention can turn thousands of electronic endoscpic systems commonly used only for routine endoscopic examination to very ***excellent, easy-to-handle*** fluorescence electronic endoscopic systems with the cheapest cost.

2. Practically, a diagnostic apparatus based on the invention of MacAulay et al. (Xillix, LIFE Fluorescence Endoscopy system, see the pictures on page 3 of my previous argument) provides the auto-fluorescence image, which comprises of only 2 colors split from the auto-fluorescence reflected from the tissue. It is practically impossible to integrate the fluorescence image with the remittance light image in case that a CCD is not placed in an endoscope, usually at its tip. The excitation light and the remittance light are alternately flashed in different timing. In order to integrate the fluorescence image with the remittance light image, the two images have to be exactly the same. Therefore, the speed of alternately flashing the excitation light and the remittance light has to be very fast and the CCD should be at the tip of an endoscope. In case that the CCD is outside the endoscope and connected onto the eyepiece part of an fiber-scope, a little move of the fiber-scope can easily made the fluorescence image different from the next coming the remittance light image, thus impossible to integrate the two images.

At present, my invention is known to be the only electronic (video)

endoscopic system that can provide real time images comprising of the fluorescence image processed on one channel and the remittance light image processed on the other two channels.

3. MacAulay et al. taught the use of a barrier filter, which is placed in front a color CCD in the endoscope tip (US5,827,190 column 9 line 61 to column 10 line 44) in their fourth embodiment. As described in my previous argument, the image obtained by their fourth embodiment is composed of only two colors, because the excitation blue light is always completely cut off by the barrier filter. Therefore, based on the knowledge taught by MacAulay et al., it is not possible to develop a fluorescence electronic (video) endoscopy system, with a CCD placed in the tip of an endoscope, that can provide images composed of 3 colors. In the second embodiment of my invention, fluorescence image processed on one RGB channel can be superimposed with the background image processed on the other two channels using an endoscope with a color CCD in its tip without using any barrier filters or dichroic mirrors.

4. The examiner asserted that it would be easy for experts in the field to develop my invention based on the knowledge taught by MacAulay et al.'660, Wagnieres et al.'227 and Longacre'758. However, the following facts prove by themselves that the examiner's assertion is not correct.

In 1989, Olympus made an application (Reference 1) of a fluorescence electronic endoscopic system to the Japanese patent and trademark office. In order to solve the problem that it is difficult to tell where the fluorescence is emitted with the very dim fluorescence image only, the concept of this invention is to superimpose the fluorescence image on the white light background image composing of 3 colors. The difference between Olympus's system and the first embodiment of my invention is just that in Olympus's system the barrier filter is not placed in front of a black and white CCD, therefore the fluorescence image is not separated from the background image on the blue light phase. Both the background and fluorescence images are processed as blue channel. This image on blue channel is then superimposed with the background image provided by green and red remittance lights processed as green and red channels. By this method, the obtained image is bright, however,

changes of fluorescence after injection of fluorescein sodium cannot be observed on real times. In order to see the changes of fluorescence, the pictures have to be recorded and analyzed by computer later (Reference 2).

In 1994, Xillix made an application on the invention of MacAulay et al.'660 to the USTPO.

In 1995, Pentax made an application (Reference 3) of a fluorescence electronic endoscopic system to the Japanese patent and trademark office. In order to solve the problem that it is difficult to tell where the fluorescence is emitted with the very dim fluorescence image only, a super-high-sensitive black and white/color CCD is placed at the endoscope tip, together with a common black and white CCD. A barrier filter is placed in front the super-high-sensitive CCD. The CCD without the barrier filter is for white light observation. The CCD with the barrier filter cutting off all excitation blue light is for observing the fluorescence image only in the blue phase of the RGB filters rotating in front the light source. The white light image and *fluorescence image* are simultaneously displayed on different monitors (Reference 4). Reference 4 shows auto-fluorescence image and fluorescence image by a fluorescent substance of an apparatus based on this application, in which a super-high-sensitive color CCD is used to observe the fluorescence image. Note that the auto-fluorescence image is composed of green color only, and fluorescence image by a fluorescent substance is composed of red and green colors only.

In 1997, Olympus made another application (Reference 5) of a fluorescence electronic endoscopic system to the Japanese patent office. In order to solve the problem that it is difficult to tell where the fluorescence is emitted with the very dim fluorescence image only and to make the apparatus simple and cheap, a broadband excitation blue light with some wave range that can pass through the barrier filter is used in addition to a narrowband excitation blue light. With the broadband excitation blue light, although the extent of the area where the fluorescence is emitted becomes somewhat blurred, the blue light that passes through the barrier filter serves as remittance light to provide the background image. As shown in Reference 6, however the obtained image is still dim. And, the price of this fluorescence endoscopic system

is still expensive, because a combination of a fiber-scope and a high sensitive color camera is used.

By References 1-6, it is obvious that it was not easy for experts in the field, such as endoscopic technicians of OLYMPUS, who already had the knowledge taught by MacAulay et al. and Longacre et al. to develop a fluorescence electronic endoscopic system with the same functions as mine. If it was easy, Olympus would never made the application of Reference 5. Please remind that:

i) Olympus has manufactured the LIFE system under the license of Xillix.

ii) A black and white CCD is used in Olympus's electronic endoscopic system for white light observation, which is, now, widely used through out the world.

iii) The fluorescence endoscopic system based on Olympus's application (Reference 5) made later to that of MacAulay et al. is still expensive and clumsy to operate. However, the image obtained is still very dim (see the color picture in Reference 6).

iv) The only difference between Olympus's previous application (Reference 1) and the first embodiment of my invention is just that a barrier filter is used in my invention but not in Olympus's.

By the way, Reference 1 and 8, together with the invention of MacAulay et al. have been discussed in an objection (Reference 7) against my Japanese patent in which three Referees finally decided that my invention is patentable (Japanese Patent No. 3809276). Three months after the referees' decision, there were no more objections. Therefore, that my invention is patentable is definite in Japan.

6. The claims in my application have been amended. The new claims have been limited to fluorescence electronic endoscopic system, in which at least one CCD, either black and white or color, is placed at the tip of an endoscope. As described above, it is impossible to make a fluorescence electronic endoscope, which can provide images composed of three colors by the knowledge taught by MacAulay et al. and Wagnieres et al., I believe that my application is now patentable with these new claims.

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By References 1-6, it is obvious that it was not easy for experts in the field, such as endoscopic techniciane of OLYMPUS, who already had the knowledge taught by MacAulay et al. and Longacre et al. to develop a fluorescence electronic endoscopic system with the same functions as mine. If it was easy, Olympus would never made the applications [illegible]

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Dear Examiner

Today, I have mailed the Amendment of the claims and the Reply to the action filed one February 9, 2005 to

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together with 7 references. They should reach your office within one week. To be sure that they reaches your office, I am faxing 7 pages of the Amendment of the claims, 6 pages of Reply to the action and 16 pages of the References (totally 30 pages including this page).

Respectfully submitted,

Ekapot Bhunachet

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